effective intraocular pressure reducing amount of a therapeutically active and physiologically acceptable prostaglandin analogue which is a selective agonist for EP_1 prostanoid receptors, or a pharmaceutically acceptable salt or ester thereof, any melanogenesis which is caused by the method of treatment being reduced as compared with that obtained by a method of treatment in which a prostaglandin analogue which is not a selective agonist for EP_1 prostanoid receptors is employed.--

--23. (New) The method according to claim 22, wherein melanogenesis is avoided.--

REMARKS

The Official Action dated September 8, 2000 has been carefully considered. Accordingly, the changes presented herewith, taken with the following remarks, are believed sufficient to place the present application in condition for allowance. Reconsideration is respectfully requested.

By the present amendment, the specification is amended to correct several typographical errors and claims 22 and 23 are added. Support for claims 22 and 23 may be found in original claim 6 and in the specification at pages 4-5. It is believed that these changes do not involve any introduction of new matter, whereby entry is believed to be in order and is respectfully requested.

Claims 1-11 and 13-21 were rejected under 35 U.S.C. §103 as being unpatentable over WO 94/08585 and the Kluender et al U.S. Patent No. 4,132,738. The Examiner asserted that the WO reference teaches the use of prostaglandin F and E in a pharmaceutical composition for the treatment of glaucoma and Kluender et al teach the use of the claimed prostaglandins in a pharmaceutical formulation. The Examiner asserted it would have been obvious to employ the teachings of the cited references.

However, as will be set forth in detail below, Applicants submit that the compositions and

methods defined by claims 1-11 and 13-21 are nonobvious over and patentably distinguishable from the combination of references cited by the Examiner. Accordingly, this rejection is traversed and reconsideration is respectfully requested.

More particularly, as defined by claim 1, the invention is directed to a composition for the treatment of glaucoma or ocular hypertension. The composition comprises a therapeutically active and physiologically acceptable prostaglandin analogue which is a selective agonist for EP_1 prostanoid receptors, or a pharmaceutically acceptable salt or ester thereof. According to claim 6, the invention is directed to a method of treating glaucoma or ocular hypertension in a subject's eye. The method comprises contacting the surface of the eye with an effective intraocular pressure reducing amount of a therapeutically active and physiologically acceptable prostaglandin analogue which is a selective agonist for EP_1 prostanoid receptors, or a pharmaceutically acceptable salt or ester thereof. Finally, according to claim 22, the invention is directed to a method of treating glaucoma or ocular hypertension in a subject's eye while reducing melanogenesis. The method comprises contacting the surface of the eye with an effective intraocular pressure reducing amount of a therapeutically active and physiologically acceptable prostaglandin analogue which is a selective agonist for EP_1 prostanoid receptors, or a pharmaceutically acceptable salt or ester thereof, and any melanogenesis which is caused by the method of treatment is reduced as compared with that obtained by a method of treatment in which a prostaglandin analogue which is not a selective agonist for EP_1 prostanoid receptors is employed.

The WO reference discloses the combination of at least one clonidine derivative and at least one prostaglandin to treat glaucoma and ocular hypertension. However, Applicants find no teaching, suggestion or recognition in the WO reference of selective agonists for EP_1 prostanoid receptors, or that the use of selective agonists for EP_1 prostanoid receptors is advantageous.

Particularly, Applicants find no teaching, suggestion or recognition in the WO reference of a method of treating glaucoma or ocular hypertension in a subject's eye and employing selective agonists for EP_1 prostanoid receptors, as recited in claim 6. Importantly, Applicants find no teaching, suggestion or recognition in the WO reference of a method of treating glaucoma or ocular hypertension in a subject's eye while reducing melanogenesis, as recited in claim 22.

The deficiencies of the WO reference are not resolved by Kluender et al. That is, Kluender et al disclose analogues of PGE_1 for selectively producing bronchodilation and decreasing gastric secretion in vivo. However, Applicants find no teaching, suggestion or recognition by Kluender et al of selective agonists for EP_1 prostanoid receptors, or that the use of selective agonists for EP_1 prostanoid receptors is advantageous. Particularly, Applicants find no teaching, suggestion or recognition by Kluender et al of a method of treating glaucoma or ocular hypertension in a subject's eye, as recited in claim 6. Importantly, Applicants find no teaching, suggestion or recognition by Kluender et al of a method of treating glaucoma or ocular hypertension in a subject's eye while reducing melanogenesis, as recited in claim 22. Thus, the mere teaching of pharmaceutical formulations by Kluender et al does not resolve the deficiencies of the WO reference.

References relied upon to support a rejection under 35 U.S.C. §103 must provide an enabling disclosure, i.e., they must place the claimed invention in the possession of the public, *In re Payne*, 203 U.S.P.Q. 245 (CCPA 1979). In view of the failure of the WO reference and Kluender et al to teach, suggest or recognize the use of selective agonists for EP_1 prostanoid receptors in a method of treating glaucoma or ocular hypertension in a subject's eye, particularly while reducing melanogenesis, the combination of the WO reference and Kluender et al does not provide an enabling disclosure of the present invention, and therefore does not support a rejection of the claims under 35 U.S.C. §103. It is therefore submitted that the rejection under

35 U.S. C. §103 has been overcome. Reconsideration is respectfully requested.

It is believed that the above represents a complete response to the Examiner's rejection, and places the present application in condition for allowance. Reconsideration and an early allowance are requested.

Respectfully submitted,

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